

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

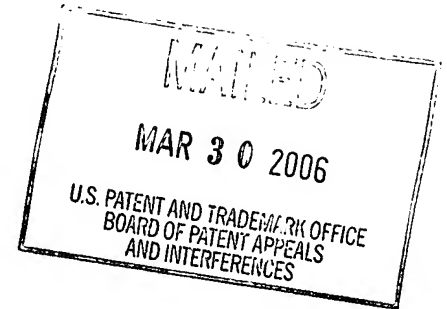
**UNITED STATES PATENT AND TRADEMARK OFFICE**

**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Ex parte KEITH R. EDWARDS

Appeal No. 2006-0392  
Application No. 10/034,981

ON BRIEF



Before ADAMS, MILLS, and GREEN, Administrative Patent Judges.

GREEN, Administrative Patent Judge.

**DECISION ON APPEAL**

An oral hearing in this case was scheduled for March 21, 2006. Upon reviewing the case, however, we have determined that an oral hearing will not be necessary and we render the following decision based on the record. See 37 CFR § 41.47(f).

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1-14. Claim 1 is representative of the subject matter on appeal, and reads as follows:

1. A method for the abortive treatment of acute migraine headache in a subject comprising administering to the subject an effective dose of intravenous valproate such that acute migraine headache is lessened or reduced in said subject.<sup>1</sup>

Claims 1-14 stand rejected under 35 U.S.C. § 103(a) as being obvious over Welch<sup>2</sup> and Walser.<sup>3</sup> After careful review of the record and consideration of the issue before us, we reverse.

### DISCUSSION

According to the rejection:

Welch teaches the administration of 800mg valproate daily for migraine headache therapy (pp. 1476-1483). The instant claims administer valproate in amounts ranging from 100 mg to 2000 mg. The 800 mg of valproate administered by the prior art lies within the range of 100 mg to 2000 mg of the instant claims.

Welch clearly teaches treating migraine headache with valproate but does not teach administering valproate by injection and effective amount in instant claim 1 can be any amount.

But Walser teaches that valproate can be administered by intravenous injection in 800 mg dosage (column 4, lines 48-53). Walser is dependent [sic, depended] upon for intravenous administration of same quantity of valproate, 800 mg, administered by Welch to treat migraine.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to intravenously administer 800 mg of valproate to treat migraine because Walser

---

<sup>1</sup> According to the examiner, the copy of claim 1 contained in the appendix to the Appeal Brief is incorrect, as the amendment after final dated November 19, 2003, was not entered. See Examiner's Answer, page 3. Thus, the claim should read as amended on February 27, 2003, and that is the version set forth above. See id.

<sup>2</sup> Welch, "Drug Therapy of Migraine," The New England Journal Of Medicine, Vol. 329, No. 20, pp. 1476-1483 (1993)

<sup>3</sup> U.S. Patent No. 5,432,176, issued July 11, 1995.

intravenously administers 800 mg of valproate. One having ordinary skill in the art would have been motivated to intravenously administer valproate since medications intravenously administered gets to the blood stream faster.

Final Rejection, mailed May 19, 2003, pages 2-3.

Appellant argues that the examiner has failed to establish a prima facie case of obviousness. See Appeal Brief, page 5. We agree, and the rejection is reversed.

The burden is on the examiner to set forth a prima facie case of obviousness. See In re Fine, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598-99 (Fed. Cir. 1988). "A rejection based on section 103 clearly must rest on a factual basis, and these facts must be interpreted without hindsight reconstruction of the invention from the prior art. In making this evaluation, all facts must be considered. The Patent Office has the initial duty of supplying the factual basis for its rejection. It may not, because it may doubt that the invention is patentable, resort to speculation, unfounded assumptions or hindsight reconstruction to supply deficiencies in its factual basis. To the extent the Patent Office rulings are so supported, there is no basis for resolving doubts against their correctness. Likewise, we may not resolve doubts in favor of the Patent Office determination when there are deficiencies in the record as to the necessary factual bases supporting its legal conclusion of obviousness." In re Warner, 379 F.2d 1011, 1017, 154 USPQ 173, 178 (CCPA 1967), cert. Denied, 389 U.S. 1057 (1968) (emphasis in original).

Claim 1 is drawn to “[a] method for the abortive treatment of acute migraine headache in a subject comprising administering to the subject an effective dose of intravenous valproate such that acute migraine headache is lessened or reduced in said subject.” As noted by the appellant, however, the Welch reference teaches that there is a distinction between the prophylactic treatment of migraine headaches and the acute treatment of migraine headaches. See Appeal Brief, page 5. Welch teaches that valproic acid is useful for the prevention of migraine headaches, but does not teach or suggest its use for the symptomatic treatment of acute migraine headaches.


The examiner argues that Welch teaches that valproate sodium is moderately effective in preventing migraine and reducing the frequency, severity and duration of severe attack as compared with placebo, and that Welch does not restrict when the valproate may be administered, which we infer to mean that the preventative treatment of the administration of valproate sodium may be administered while the patient has a migraine headache. The examiner does not address, however, why one of ordinary skill in the art would take an oral preventative treatment, given daily, and administer it intravenously. The rationale given in the rejection, i.e., since medications intravenously administered get to the blood stream faster, applies to the symptomatic treatment required by claim 1 and not to the preventative treatment taught by Welch. Thus, it appears that the examiner has impermissibly used hindsight to combine the references to arrive at the claimed invention. Moreover, as further

noted by the appellant, Walser is drawn to the intravenous administration of valproate in the treatment of chronic renal failure, but does not teach or suggest its use for other indications. See Appeal Brief, page 8.

CONCLUSION

Because the examiner has failed to set forth a prima facie case of obviousness, the rejection under 35 U.S.C. § 103(a) is reversed.

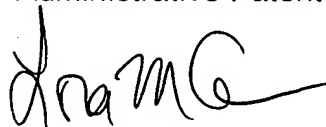
REVERSED



Donald E. Adams  
Administrative Patent Judge



Demetra J. Mills  
Administrative Patent Judge



Lora M. Green  
Administrative Patent Judge

)  
)  
)  
)  
) BOARD OF PATENT  
)  
) APPEALS AND  
)  
) INTERFERENCES  
)  
)

Appeal No. 2006-0392  
Application No. 10/034,981

Page 6

LAHIVE & COCKFIELD  
28 STATE STREET  
BOSTON MA 02109